

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment submitted March 17, 2011. Claims 1 and 3 are amended. Claims 2, 32, and 41 were previously cancelled (Applicant previously cancelled withdrawn claims 43, 54, and 63). Claims 1—10, 31, 33 – 40 are presented for examination. Note: Claims 11 – 30, 42, 44 – 53, and 55 – 63 were previously withdrawn.

Claim Objections

2. Claim 1 is objected to because of the following informalities: An incorrect claim status identifier was applied to claim 1. Appropriate correction is required
3. The objection to claim 3 is hereby withdrawn based upon the amendment submitted March 17, 2011.

Claim Rejections - 35 USC § 112

4. The 35 U.S.C. 112, second paragraph rejection of claim 1 is hereby withdrawn based upon the amendment submitted March 17, 2011.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1 and 3 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (U.S. Patent Number 5,594,638) in view of Ohayon et al., herein after Ohayon (U.S. Patent Number 4,712,562) further in view of Brown (U.S. Publication Number 2003/0069753).

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In regard to claim 1 (Previously Presented), Iliff teaches a system for determining whether a person should have health care professional attention and for providing clinical notes to a caregiver, the system comprising: a monitoring device having a microprocessor operably coupled to a memory unit (column 7, line 63), an input device (column 4, lines 39 – 49), an output device (column 4, lines 39 – 49), and a communication device (column 7, lines 49 – 62), the memory unit being programmed with a set of instructions for posing questions to the person via the output device (column 6, lines 34 – 44), and, receiving answers from the person via the input device (column 6, lines 34 – 37).

Iliff fails to teach a system comprising: the remote computer being programmed to determine whether the person should have health care professional attention based at least in part upon the answers; a system comprising transmitting the answers to a remote computer via the communication device; and a remote computer programmed to: receive the answers from the monitoring device; determine, for each of the questions, whether the answer to the question satisfies a condition associated with the question; and when the answer satisfies the condition, search a datastore accessible by the remote computer for textual phrases that match the question and automatically generate a clinical note containing the textual phrases for review by the health care professional.

Ohayon teaches a system comprising: the remote computer (Figure 1; column 3, line 56 through column 4, line 4; and column 4, lines 14 – 34) being programmed to determine whether the person should have health care professional attention based at least in part upon the answers (Figure 1; column 3, line 56 through column 4, line 27).

Iliff and Ohayon fail to teach a system comprising: transmitting the answers to a remote computer via the communication device; and a remote computer programmed to: receive the answers from the monitoring device; determine, for each of the questions, whether the answer to the question satisfies a condition associated with the question; and when the answer satisfies the condition, search a datastore accessible by the remote computer for textual phrases that match the question and automatically generate a clinical note containing the textual phrases for review by the health care professional.

Brown teaches a system comprising transmitting the answers to a remote computer via the communication device (paragraph [0040] where the answers to queries are transmitted from a personal

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monitoring device to a computer via the web, thus the computer is remote from the device); and a remote computer programmed to: receive the answers from the monitoring device (paragraphs [0040] and [0041]); determine, for each of the questions, whether the answer to the question satisfies a condition associated with the question (Figures 5, 6A, 8, and 10); and when the answer satisfies the condition, search a datastore accessible by the remote computer for textual phrases that match the question (Figure 5 where the answer satisfies the question and additional comments related to the answer may be presented as shown in Appendix d, page 61) and automatically generate a clinical note (Figure 2; paragraphs [0044], [0105], and [0115]) containing the textual phrases (paragraph [0044]) for review by the health care professional (paragraph 41 and appendix D, page 18). The text may be customized per the script so the physician may input any type of phrase or text. The screen shot of the report shown in Appendix D, page 61 is merely an example of the type of response available.

It would have been obvious to one of ordinary skill in the art to include in the computerized medical diagnostic system of Iliff the ability to monitor outpatients of Ohayon with the remote health monitoring system taught by Brown since the claimed invention is merely a combination of old elements, and in the combination each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable. Ohayon and Brown provide medical monitoring systems, while Iliff provides a medical diagnostic and treatment system; it would be obvious to combine the inventions as all are directed towards the diagnosis, treatment, and monitoring of a patient electronically.

In regard to claim 3 (Currently Amended), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the datastore also stores a symptom identifier associated with each of the questions posed to the person via the monitoring device (column 7, line 63 through column 8, line 42), wherein the remote computer is programmed to select a grammatical rule for construction of the clinical note based upon the symptom identifier (column 8, lines 27 – 28). The Examiner interprets a grammatical rule to be a system which inserts canned or pre-programmed text into a report or summary so as to link symptoms identified by the patient.

In regard to claim 4 (Original), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the clinical note comprises verbiage presenting symptoms reported by the person via the input device (column 8, lines 27 – 28).

In regard to claim 5 (Previously Presented), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer is further programmed to generate the clinical note based upon the measurement transmitted to the remote computer (column 28, lines 19 – 34).

Iliff fails to teach a system wherein: the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor and the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer; and the remote computer is further programmed to generate a clinical note based upon the measurement transmitted to the remote computer.

Ohayon teaches a system to transmit the measurement to the remote computer (column 4, line 51 through column 5, line 10); and the remote computer is further programmed to generate a clinical note based upon the measurement transmitted to the remote computer (column 4, lines 14 – 34).

Iliff and Ohayon fail to teach a system wherein: the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor and the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient.

Brown teaches a system wherein: the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor (paragraph [0090]) and the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer (paragraph [0090]).

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The motivation to combine the teachings of Iliff, Ohayon and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 6 (Original), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer is further programmed to present a user interface that permits viewing of the clinical note and also permits viewing of a populace of persons identified as potentially needing attention by a health care professional (column 6, lines 38 – 44).

In regard to claim 7 (Previously Presented), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer communicates the clinical note to a health care professional (column 28, lines 27 - 29). Iliff fails to teach a remote computer, however, this feature is taught by Ohayon.

Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 4 and column 4, lines 14 - 34).

The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 8 (Previously Presented), Iliff, Ohayon, and Brown teach the system of claim 7.

Iliff fails to teach a system wherein the remote computer communicates the clinical note to the health care professional via e-mail.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 4 and column 4, lines 14 - 34).

Iliff and Ohayon fail to teach a system wherein the computer communicates the clinical note to the health care professional via e-mail.

Brown teaches a system wherein the computer communicates the clinical note to the health care professional via e-mail (appendix: page 105).

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The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 9 (Original), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer is further programmed to present questions to be posed to the person using the monitoring device, the questions being used to verify the determination that the person should have health care professional attention (column 2, lines 41 – 48 and column 35, lines 33 – 42), however Iliff fails to teach a remote computer.

Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 through column 4, line 4 and column 4, lines 14 - 34).

The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 10 (Original), Iliff, Ohayon, and Brown teach the system of claim 1. Iliff further teaches a system wherein the remote computer is further programmed to provide a user interface (column 6, lines 38 – 44) permitting selection of a disease state for monitoring by the monitoring device (column 50, lines 53 – 58), however, however Iliff fails to teach a remote computer.

Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (column 3, line 56 through column 4, line 4).

The motivation to combine the teachings of Iliff, Ohayon, and Brown is discussed in the rejection of claim 1, and incorporated herein.

7. Claims 31 and 33 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (U.S. Patent Number 5,594,638) and Ohayon et al., herein after Ohayon (U.S. Patent Number 4,712,562) in view of Brown (U.S. Publication Number 2003/0069753) further in view of Luttrell (U.S. Publication Number 2003/0004758 A1).

In regard to claim 31 (Previously Presented), Iliff teaches a system for determining whether a person should have health care professional attention, the system comprising: a monitoring device having a microprocessor operably coupled to a memory unit (column 7, line 63), an input device (column 4, lines 39 – 49), an output device (column 4, lines 39 – 49), and a communication device (column 7, lines 49 – 62), the memory unit being programmed with a set of instructions for posing questions to the person via the output device (column 6, lines 34 – 44), and receiving answers from the person via the input device (column 6, lines 34 – 37).

Iliff fails to teach a system comprising: transmitting the answers to a remote computer via the communication device; the remote computer being programmed to: receive the answers from the monitoring device; determine whether the person should have health care professional attention based at least in part upon the answers; and automatically create an entry in an intervention data field for the person, the entry describing a treatment to counteract a symptom experienced by the person.

Ohayon teaches a system comprising: the remote computer (Figure 1; column 3, line 56 through column 4, line 4; and, column 4, lines 14 – 34) being programmed to; determine whether the person should have health care professional attention based at least in part upon the answers (Figure 1; column 3, line 56 through column 4, line 4; and, column 4, lines 14 – 34).

Iliff and Ohayon fail to teach a system comprising: transmitting the answers to a remote computer via the communication device; receive the answers from the monitoring device; and automatically create an entry in an intervention data field for the person, the entry describing a treatment to counteract a symptom experienced by the person.

Brown teaches a system comprising: transmitting the answers to a remote computer via the communication device (paragraph [0040]); and receive the answers from the monitoring device (paragraphs [0040] and [0041]).

Iliff, Ohayon, and Brown fail to teach a system comprising: automatically create an entry in an intervention data field for the person, the entry describing a treatment to counteract a symptom experienced by the person.

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Luttrell discloses a system comprising: automatically create an entry in an intervention data field for the person, the entry describing a treatment to counteract a symptom experienced by the person (paragraphs 53 and 58) where automatic compilation of treatment data is created.

It would have been obvious to one of ordinary skill in the art to include in the computerized medical diagnostic system of Iliff the ability to monitor outpatients of Ohayon and the remote health monitoring system as taught by Brown with the system of recording patient treatment of Luttrell since the claimed invention is merely a combination of old elements, and in the combination each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

In regard to claim 33 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 31.

Iliff fails to teach a system wherein the entry data further includes the date upon which the remote computer system created the entry.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 though column 4, line 27 and column 4, lines 14 - 34).

Iliff and Ohayon fail to teach a system wherein the entry data further includes the date upon which the computer system created the entry.

Brown teaches a system wherein the entry data further includes the date upon which the computer system created the entry (appendix: Figure 2, page 23).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 34 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 33.

Iliff and Ohayon fail to teach a system wherein the entry data further includes an indication of whether or not the treatment has counteracted the symptom.

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Brown further teaches a system wherein the entry data further includes an indication of whether or not the treatment has counteracted the symptom (appendix: Figure 6, page 27).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 35 (Original), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 31. Iliff further teaches a system wherein the remote computer is further programmed to present a user interface that permits viewing of a populace of persons identified as potentially needing attention by a health care professional (column 6, lines 38 - 44).

In regard to claim 36 (Original), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 31. Iliff further teaches a system wherein the remote computer system is further programmed to present an operator with a set of questions, so that the operator may pose the questions to the person using the monitoring device, in response to the person having been identified as potentially needing attention by a health care professional (column 35, lines 11 - 42); wherein the set of questions are designed to permit a conclusion to be drawn regarding a diagnosis of a symptom reported by the person using the device (column 40, lines 41 – 56); and wherein the set of questions are designed to permit a conclusion to be drawn regarding selection of an intervention appropriate for the diagnosis (column 40, lines 41 – 56 and column 41, lines 46 – 62). However, Iliff fails to teach a remote computer.

Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 though column 4, line 27).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 37 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 36. Iliff further teaches a system wherein the remote computer is further programmed to arrive at a preliminary diagnosis and a preliminary intervention as a function of the person's answers to the

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questions posed by the operator (column 39, line 7 through column 42, line 9). However, Iliff fails to teach a remote computer.

Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 though column 4, line 27).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 38 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 37. Iliff further teaches a system wherein the remote computer is further programmed to generate a clinical note based upon the preliminary diagnosis and the preliminary intervention (column 28, lines 19 – 34).

Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 though column 4, line 27).

Brown teaches a clinical note containing textual phrases (paragraph [0044]).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

In regard to claim 39 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 36. Iliff teaches a system wherein the remote computer chooses the set of questions based upon the answers transmitted to the remote computer by the monitoring device (column 39, line 7 through column 42, line 9).

Iliff fails to teach a remote computer.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 though column 4, line 27).

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

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In regard to claim 40 (Previously Presented), Iliff, Ohayon, Brown, and Luttrell teach the system of claim 36.

Iliff fails to teach a system wherein the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor; the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the remote computer; and the remote computer is further programmed to choose the set of questions based upon the answers transmitted to the remote computer and the measurement taken by the biometric measurement unit.

Ohayon teaches a remote computer (Figure 1; column 3, line 56 though column 4, line 27).

Iliff and Ohayon fail to teach a system wherein the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor; the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the computer; and the computer is further programmed to choose the set of questions based upon the answers transmitted to the computer and the measurement taken by the biometric measurement unit.

Brown teaches a system wherein the monitoring device further comprises a biometric measuring unit operably coupled to the microprocessor (paragraph [0090]); the memory unit in the monitoring device is further programmed with a set of instructions to cause the biometric measuring unit to take a measurement of the patient, and to transmit the measurement to the computer; and the remote computer is further programmed to choose the set of questions based upon the answers transmitted to the remote computer and the measurement taken by the biometric measurement unit.

The motivation to combine the teachings of Iliff, Ohayon, Brown, and Luttrell is discussed in the rejection of claim 31, and incorporated herein.

Response to Arguments

8. Applicant's arguments filed March 17, 2011 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed March 17, 2011.

Claim Rejections Under 35 U.S.C. §103(a)**Claims 1 and 3 - 10**

The Applicant argues the Examiner fails to establish a *prima facie* case of obviousness. The Examiner respectfully disagrees. The Examiner submits in response to applicant's argument that there is no suggestion to combine the references and that the Office has not made a *prima facie* case of obviousness, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it has been clearly set forth above in the 35 U.S.C. 103(a) rejections of the claims that there is motivation for combining the references (Iliiff in view of Chayon further in view of Brown) and therefore the Office takes the position that a *prima facie* case of obviousness has been made.

The Applicant argues Brown does not disclose "searching a datastore accessible by the remote computer for textual phrases that match the question." The Examiner respectfully disagrees. The Examiner submits Brown discloses queries into a patient's health with patient responses; a comment is generated based on patient's health, thus implying a database was searched for phrases related to a patient's response (Appendix D, page 27). Therefore, the Applicant's argument is not persuasive.

The Applicant argues Brown does not disclose "automatically generat[ing] a clinical note containing the textual phrases for review by the health care professional." The Examiner respectfully disagrees. The Examiner submits Brown discloses a report generator connected to a database for generating a report of the measurements and responses (paragraph 44). In addition, Appendix D – Alternative User Interface (page 61) illustrates an example of textual phrases associated with a patient's

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response in a report and/or graphical formats. Thus, Applicant's argument is not persuasive as Brown discloses automatically generating a clinical note (i.e. report) where the text may be customized per script so the physician may input any type of phrase of script.

The Applicant argues Brown does not disclose searching for textual phrases. The Examiner respectfully disagrees. The Examiner submits the Applicant's argument was addressed in the above responses, and is incorporated herein.

Claims 31 and 33 - 40

The Applicant argues Luttrell teaches away from Applicant's claim 1; The Applicant argues the suggested combination of Iliff, Ohayon, Brown, and/or Luttrell is improper because cannot be combined where the references teach away from their combination specifically Luttrell data entry after evaluation. The Examiner respectfully submits that is not evidence that the applied references teach away from applicant invention. Furthermore, it is respectfully submitted that if Applicant's were correct in his assertion which Examiner does not admit, it has been held that prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Luttrell discloses entering information concerning a patient evaluation through an interactive/user interface (paragraph 19). A treatment goal is identified based on an evaluation of a patient's condition (signs and symptoms exhibited by a patient) and may take place prior to the current treatment session (paragraph 27). Thus, Applicant's argument is not persuasive as Luttrell discloses determining a treatment based on an evaluation of a patient's signs and symptoms, as does the present application.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 3:30 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on 571-272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3626

/K. R./
Examiner, Art Unit 3626